## REMARKS

### I. Status of the Claims

Claims 1-101 were filed with the application. Claims 1-58, 60, 63-69 and 71-101 have been canceled. Thus, claims 59, 61, 62 and 70 are under consideration and have been examined. Claim 59 is amended. Thus, claims 59 (amended), 61, 62 and 70 are presented for reconsideration.

All claims are rejected under 35 U.S.C. §112, second paragraph. Claims 59[1] and 70 stand rejected under 35 U.S.C. §112, first paragraph for alleged "new matter." All claims stand rejected under 35 U.S.C. §102 and 35 U.S.C. §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

### II. Rejections Under 35 U.S.C. §112, Second Paragraph

The examiner has rejected claims 59, 61, 62 and 70 under the second paragraph of §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The examiner again objects to use of the word "modulation" as not defining whether the regulation is up or down. Applicants have previously provided an adequate response to this rejection. A Notice of Appeal is filed to address the maintenance of the rejection.

Claim 70 is rejected over the term "second pharmaceutical agent." Applicants previously amended claim 70 to clarify that the second pharmaceutical agent is distinct from the agent provided in claim 59. Now, applicants have further amended claim 59 to specify a first pharmaceutical agent in that claim. Reconsideration and withdrawal of the rejection is respectfully requested.

## III. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 59[2] and 70 are newly rejected under the first paragraph of §112 as introducing new matter into the claims. The alleged new matter is the inclusion of the terms "selecting" and "human subject" in claim 59, and "human subject" in claim 70. Applicants traverse.

In order to meet the written description requirements of 112 for amended claims, the description must "reasonably [convey] to the artisan that the inventor had possession at that time of the later claimed subject matter." *TurboCare Div. Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 264 F.3d 1111, 1118, 60 U.S.P.Q.2d 1017, 1022 (Fed. Cir. 2001). An amendment by itself does not constitute new matter "unless it discloses an 'invention, process, or apparatus not theretofore described.'" *Triax Co. v. Hartman Metal Fabricators, Inc.*, 479 F.2d 951, 956-957, 178 U.S.P.Q. 142, 146 (2d Cir. 1973). If an amendment is made merely to render explicit what had been implicitly disclosed originally, the fact that new language is added does not make the new language ipso facto new matter. *In re Wright*, 343 F.2d 761, 767, 145 U.S.P.Q. 182, 188 (CCPA 1965). Therefore, the fundamental inquiry is whether the original application supports the amended matter. *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347, 1352, 55 U.S.P.Q.2d 1650, 1653 (Fed. Cir. 2000). The specification "need not describe the claimed subject matter in exactly the same terms as used in the claims" in order to comply with the written description requirement. *All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002). Furthermore, "the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one

[1] The Office Action states that claim 1 is rejected, but this claim has been canceled. It is believed the rejection is over claim 59 instead.
[2] The Office Action states that claim 1 is rejected, but this claim has been canceled. It is believed the rejection is over claim 59 instead.

skilled in the art would recognize . . . that the new language reflects what . . . has been invented." *Id.*

Applicants respectfully contend that the inclusion of the terms "human subject" in claim 59, and "human subject" in claim 70, in no way constitutes new matter. The use of the term "human subject" is clearly supported by the specification. For example, page 17, line 4 of the specification states, "[c]urrent results indicate that the interaction between MCIP and calcineurin is pertinent to the pathobiology, and ultimately to the therapy, of ***human disease***." Emphasis added. Page 34, line 19 of the specification states, "[a]ntisense RNA constructs, or DNA encoding such antisense RNA's, may be employed to inhibit gene transcription or translation or both within a host cell, either *in vitro* or *in vivo*, such as within a host animal, including a ***human subject***." Emphasis added. These statements unequivocally support the use of the invention in a human subject.

Regardless, the specification need not even use the same language as in the claims as long as one skilled in the art would understand that the applicant had invented what is claimed. *All Dental Prodx*, 309 F.3d at 779, 64 U.S.P.Q.2d at 1948. An entire section beginning at page 68, line 19 of the specification, is devoted to the administration of the invention to ***patients***. The last sentence of this section states that, "for ***human*** administration, preparation should meet sterility, pyrogenicity, general safety and purity standards as required by the FDA Office of Biologics standards" making it abundantly clear that the term patients is synonymous with human subjects. One skilled in the art would easily understand "patients" to be human subjects rather than animal subjects. Additionally, page 6, line 25 states that the modulator is to be administered to a muscle cell. On the following page, the next sentence is "[t]he muscle cell may be located in a ***mammal***." Emphasis added. Viewed in this context, the specification supports the

administration of a modulator to a mammal. One skilled in the art would undoubtedly know that human beings are mammals and understand that the modulator could be administered to human subjects. Thus, in light of the specification, the use of the term "human subject" does not constitute new matter under §112.

Applicants also disagree that the term "selecting" is, in any way, new matter. Pages 67, lines 1-10 in the specification discusses four possible agents that may be chosen to modulate MCIP function and states "[modulation] may be accomplished in ***one*** of several ways." Emphasis added. The claim calls for giving the patient "***a*** modulator of MCIP expression" as in the singular sense. One skilled in the art would understand that a physician or health care provider would have to choose one of the modulators *i.e.* ***select*** a modulator, rather than give the patient all the possible compounds. Furthermore, the specification discloses use of a modulator in combination with another pharmaceutical agent on page 67. The specification describes situations where "the other agent and expression construct are applied separately." Significantly, the term "expression construct" is expressed in a singular sense. Page 68, line 7 states, "it is also conceivable that more than one administration of ***either*** a MCIP-1 or MCIP-2 gene . . . will be desired." Emphasis added. Therefore, one of the MCIP modulators is selected and administered rather than both of the possible modulators.

As stated before, the specification need not specifically mention a limitation as long as one skilled in the art would recognize what has been invented. *All Dental Prodx*, 309 F.3d at 779, 64 U.S.P.Q.2d at 1948. Plainly, one skilled in the art would implicitly construe these statements as selecting one type of MCIP modulator.

Thus, as should be evident from the foregoing discussion, neither of the questioned term constitutes new matter under §112, first paragraph. Reconsideration and withdrawal of the rejection is respectfully requested.

## IV. Rejections Under 35 U.S.C. §102

Claims 59-62 are again rejected under 35 U.S.C. §102(a) as being anticipated by Fuentes *et al.* (July 1, 2000). Applicants previously submitted an Inventors' Declaration under 37 C.F.R. §1.131 to swear behind this reference. The examiner alleges that only unsigned declarations were submitted. This is not true, as illustrated by the attached materials, which were submitted on July 1, 2003. **IF THE EXAMINER CANNOT, ONCE AGAIN, FIND THESE MATERIALS, A CALL TO THE UNDERSIGNED IS REQUESTED.** Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 59-62 are again rejected under 35 U.S.C. §102(a) as being anticipated by Rothermel *et al.* (2000). In response, applicants submitted an Inventor's Declaration under 37 C.F.R. §1.132, explaining that the authors of the paper are the current inventors, and that no other authors listed on the papers contributed inventively to the presently claimed invention. The examiner alleges that only unsigned declarations were submitted. This is not true, as illustrated by the attached materials, which were submitted on July 1, 2003. **IF THE EXAMINER CANNOT, ONCE AGAIN, FIND THESE MATERIALS, A CALL TO THE UNDERSIGNED IS REQUESTED.** Reconsideration and withdrawal of the rejection is respectfully requested.

## V. Rejections Under 35 U.S.C. §103

Claims 59, 60 and 70 are rejected as obvious over (i) Chin *et al.* in view of Rothermel *et al.*, and (ii) Sussman *et al.* in view of Yang *et al.* Applicants traverse. Neither Rothermel nor Yang are available for combination with Chin and Sussman. The Rule 131 affidavit (previously submitted on July 1, 2003) has established an invention date prior to the publication of Yang, removing this as "prior" art. The Rule 132 affidavit established that Rothermel is not "by another," and hence unavailable as a reference against the instant claims. Reconsideration and withdrawal of the rejection is respectfully requested.

## VI. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to this effect is earnestly solicited. Should Examiner Liu have any questions regarding this response, he is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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